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system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional. The system is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic.

(b) *Classification.* Class II (special controls). The special control is: The FDA guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System." See § 880.1(e) for availability of this guidance document.

[72 FR 59177, Oct. 19, 2007]

§ 880.6320 AC-powered medical examination light.

(a) *Identification.* An AC-powered medical examination light is an AC-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38806, July 25, 2001]

§ 880.6350 Battery-powered medical examination light.

(a) *Identification.* A battery-powered medical examination light is a battery-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice require-

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ments of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6375 Patient lubricant.

(a) *Identification.* A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.

(b) *Classification.* Class I (general controls).

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 46952, Sept. 10, 2001]

§ 880.6430 Liquid medication dispenser.

(a) *Identification.* A Liquid medication dispenser is a device intended for medical purposes that is used to issue a measured amount of liquid medication.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6450 Skin pressure protectors.

(a) *Identification.* A skin pressure protector is a device intended for medical purposes that is used to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient's developing decubitus ulcers (bedsores).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation

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in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6500 Medical ultraviolet air purifier.

(a) *Identification.* A medical ultraviolet air purifier is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation.

(b) *Classification.* Class II (performance standards).

§ 880.6710 Medical ultraviolet water purifier.

(a) *Identification.* A medical ultraviolet water purifier is a device intended for medical purposes that is used to destroy bacteria in water by exposure to ultraviolet radiation.

(b) *Classification.* Class II (performance standards).

§ 880.6730 Body waste receptacle.

(a) *Identification.* A body waste receptacle is a device intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[66 FR 38806, July 25, 2001]

§ 880.6740 Vacuum-powered body fluid suction apparatus.

(a) *Identification.* A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles,

suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.6760 Protective restraint.

(a) *Identification.* A protective restraint is a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.

(b) *Classification.* Class I (general controls).

[61 FR 8439, Mar. 4, 1996, as amended at 66 FR 46952, Sept. 10, 2001]

§ 880.6775 Powered patient transfer device.

(a) *Identification.* A powered patient transfer device is a device consisting of a wheeled stretcher and a powered mechanism that has a broad, flexible band stretched over long rollers that can advance itself under a patient and transfer the patient with minimal disturbance in a horizontal position to the stretcher.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.6785 Manual patient transfer device.

(a) *Identification.* A manual patient transfer device is a device consisting of a wheeled stretcher and a mechanism on which a patient can be placed so that the patient can be transferred with minimal disturbance in a horizontal position to the stretcher.

(b) *Classification.* Class I (general controls). The device is exempt from the